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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,266	08/27/2001	Gust H. Bardy	032580.0028.CIP1	5571

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EXAMINER	
DROESCH, KRISTEN L	

ART UNIT	PAPER NUMBER
3762	7

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,266	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28, and 31-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 28 recites the limitation "the lead system" in line 1.

Claim 31 recites the limitations "the power supply" in line 6, and "the capacitor" in lines 9-10.

Claim 58 recites the limitation "the lead system" in lines 1-2.

There is insufficient antecedent basis for these limitations in these claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 29-31, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey III et al. (5,318,591).

Regarding claims 1 and 31, Causey III et al. shows a power supply or voltage output system comprising a capacitor subsystem and a battery subsystem (62) electrically coupled to the capacitor subsystem (Col. 2, lines 35-56; Col. 3, lines 21-41).

With respect to claims 29-30 and 59-60, Causey III et al. shows the pacing energy comprises burst or ramp pacing energy (Col. 8, lines 41-45).

6. Claims 1-3, 15, 20-21, 23, 27, 31-33, 45, 50-51, 53 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein (4,406,286).

Regarding claims 1 and 31, Stein shows a power supply or voltage output system comprising a capacitor subsystem (17) and a battery subsystem electrically coupled to the capacitor subsystem (Col. 4, lines 41-43).

With respect to claims 2-3, and 32-33, Stein shows the pacing energy comprises a bi-phasic waveform having a peak voltage that is approximately 5 Volts to approximately 500 Volts or approximately 5 Volts to approximately 25 Volts (Fig. 3; Col 4, lines 2-7, lines 41-43; Col. 6, lines 51-66). The supply voltage of 2.8 V doubled is equal to 5.6 V.

Regarding claims 15, and 45, Stein shows the bi-phasic waveform having a pulse width between approximately 2 ms and approximately 40 ms (Col. 10, lines 55-58). If the recharge period T_{FR} is set ordinarily at 6-12 ms, the delay interval T_D is 0.5 ms, and the pulse period T_P appears to be shorter that the recharge period T_{FR} in Fig. 3, then the maximum total pulse width of the bi-phasic pulse is 24.5 ms, if it is assumed that the recharge period T_{FR} is set at the maximum of 12 ms and the pulse period T_P is equal to the recharge period T_{FR}.

With respect to claims 20-21, 23, 50-51, and 53, Stein shows the pacing energy comprises a bi-phasic waveform comprising a positive portion and negative portion each having a tilt of approximately 10% to approximately 90% (Fig. 3).

Regarding claims 27, and 57, it is inherent that Stein shows the biphasic waveform is provided after a patient's heart rates is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

7. Claims 1, 27-29, 31, 28, 53, 57-59, 61, 87-89, 91, and 117-119 are rejected under 35 U.S.C. 102(e) as being anticipated by KenKnight (6,148,230).

Regarding claims 1, 31, and 61, KenKnight shows an ICD comprising a housing having an electrically conductive surface on an outer surface of the housing; a lead assembly (20) coupled to the housing which does not directly contact the patient's heart or reside in the intrathoracic blood vessels; a capacitor subsystem located within the housing and electrically coupled to the electrically conductive surface of the electrode and a battery subsystem electrically coupled to the capacitor subsystem (Col. 1, lines 49-58; Col. 3, lines 60-62; Col. 4, lines 25-28; Col. 4, lines 42-50).

Regarding claims 27, 57, 87, and 117, it is inherent that KenKnight shows the biphasic waveform is provided after a patient's heart rates is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

With respect to claims 28, 58, 88, and 118, KenKnight shows the lead system comprises an electrode proximate the sternum and anterior to the heart (Col. 3, lines 9-19).

Regarding claims 29, 59, 89, and 119, KenKnight shows the pacing energy comprises burst pacing energy (Col. 2, lines 54-58).

With respect to claim 91, KenKnight shows a method for supplying power to an ICD and for providing pacing energy for an ICD positioned subcutaneously between the third and twelfth rib and using a lead assembly (20) which does not directly contact the patient's heart or reside in the intrathoracic blood vessels comprising generating pacing energy, storing pacing energy, and delivering pacing energy to a patient's heart (Col. 1, lines 49-58; Col. 3, lines 60-62; Col. 4, lines 25-28; Col. 4, lines 42-50).

The functional language and introductory statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4-14, 16-19, 22, 24, 34-44, 46-49, 52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein (4,406,286).

Regarding claims 4-14, and 34-44 Stein discloses the claimed invention except for the bi-phasic waveform having a peak voltage of approximately 25 Volts to

approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, approximately 75 Volts to approximately 100 Volts, approximately 100 Volts to approximately 150 Volts, approximately 150 Volts to approximately 200 Volts, approximately 200 Volts to approximately 250 Volts, approximately 250 Volts to approximately 300 Volts, approximately 300 Volts to approximately 350 Volts, approximately 350 Volts to approximately 400 Volts, approximately 400 Volts to approximately 450 Volts, and approximately 450 Volts to approximately 500 Volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the bi-phasic waveform peak voltage as taught by Stein with the bi-phasic waveform peak voltages of 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, approximately 75 Volts to approximately 100 Volts, approximately 100 Volts to approximately 150 Volts, approximately 150 Volts to approximately 200 Volts, approximately 200 Volts to approximately 250 Volts, approximately 250 Volts to approximately 300 Volts, approximately 300 Volts to approximately 350 Volts, approximately 350 Volts to approximately 400 Volts, approximately 400 Volts to approximately 450 Volts, and approximately 450 Volts to approximately 500 Volts, since applicant has not disclosed that these particular bi-phasic waveform peak voltages provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform peak voltage such as 5.6 V taught by Stein for pacing the heart.

With respect to claims 16-19, and 46-49, Stein discloses the claimed invention except for the bi-phasic waveform having a pulse width between approximately 2 ms and approximately 10 ms, approximately 10 ms and approximately 20 ms, approximately 20

ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify bi-phasic waveform pulse width as taught by Stein with bi-phasic waveforms having a pulse width between approximately 2 ms and approximately 10 ms, approximately 10 ms and approximately 20 ms, approximately 20 ms and approximately 30 ms, approximately 30 ms and approximately 40 ms, since applicant has not disclosed that these particular bi-phasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform pulse width such as approximately 6.5 ms to approximately 24.5 ms taught by Stein for applying pacing pulses.

Regarding claims 22, 24, 52, and 54, Stein discloses the claimed invention except for the positive and negative voltage portion of the bi-phasic waveform having a tilt of 50%. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the tilt of the positive and negative voltage portion of the bi-phasic waveform as taught by Stein with a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any tilt such as the 10%-90% tilt taught by Stein for applying pacing pulses.

10. Claims 25, 26, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein (4,406,286) in view of Florio et al. (6,519,493). Stein is as explained before. Although Stein fails to shows the bi-phasic pacing pulses are applied at a rate of approximately 100 to approximately 300 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who

teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the pacing pulses of Stein at a rate of 155 bpm or more after detection of a tachycardia or 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

11. Claims 61-63, 75-77, 80, 92-93, 105-107, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Herscovici (4,534,956). Although KenKnight fails to show utilizing a bi-phasic pacing pulse, attention is directed to Herscovici who shows utilizing a bi-phasic pacing pulse having a positive and negative pulse and a peak voltage of approximately 5 V to approximately 500 V and approximately 5 V to approximately 25 V and a duration of from approximately 2 ms to approximately 40 ms, from approximately 2 ms to approximately 10 ms, and from approximately 10 ms to approximately 20 ms (Col. 3, lines 25-45; Col. 63-68). Herscovici teaches that utilizing a bi-phasic waveform allows sensing of an evoked response of the heart because the electrical charges are balanced by using a bi-phasic waveform (Col. 1, line 9-Col. 2, line 36). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize a bi-phasic pacing pulse having a positive and negative pulse and a peak voltage of approximately 5 V to approximately 500 V and approximately 5 V to approximately 25 V and a duration of from approximately 2 ms to approximately 40 ms, from approximately 2 ms to approximately 10 ms, and from approximately 10 ms to approximately 20 ms as

Herscovici teaches in order to enable sensing of an evoked response due to the electrical charge balance by using a bi-phasic waveform. The peak voltage would be between 6 V and 21 V based Ohm's law (V=IR) and the fact that the impedance is between 200-700 ohms and the current is 30 mA. The total pulse width varies between 5.5 ms and 19.8 ms due to the T_s being between 0.5 ms and 1.8 ms and T_c being ten times as great as T_s.

12. Claims 64-74, 70-71, 95-104, and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Herscovici (4,534,956). KenKnight and Herscovici are as explained before.

Regarding claims 64-74,78-79, 95-104, and 109-109, KenKnight and Herscovici disclose the claimed invention except for the bi-phasic waveform has a peak voltage of approximately 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, approximately 75 Volts to approximately 100 Volts, approximately 100 Volts to approximately 150 Volts, approximately 150 Volts to approximately 200 Volts, approximately 200 Volts to approximately 250 Volts, approximately 250 Volts to approximately 300 Volts, approximately 300 Volts to approximately 350 Volts, approximately 350 Volts to approximately 400 Volts, approximately 400 Volts to approximately 450 Volts, and approximately 450 Volts to approximately 500 Volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the bi-phasic waveform peak voltage as taught by KenKnight and Herscovici with bi-phasic waveform peak voltages of 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, approximately 75 Volts to approximately 100 Volts, approximately 100 Volts to approximately 150 Volts, approximately 150 Volts to

approximately 200 Volts, approximately 200 Volts to approximately 250 Volts, approximately 250 Volts to approximately 300 Volts, approximately 300 Volts to approximately 350 Volts, approximately 350 Volts to approximately 400 Volts, approximately 400 Volts to approximately 450 Volts, and approximately 450 Volts to approximately 500 Volts since applicant has not disclosed that these particular bi-phasic waveform peak voltages provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform peak voltage such 5.6 V taught by KenKnight and Herscovici for pacing the heart.

With respect to claims 78-79, and 108-109, KenKnight and Herscovici disclose the claimed invention except for the bi-phasic waveform having a pulse width between approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify bi-phasic waveform pulse width as taught by KenKnight and Herscovici with bi-phasic waveforms having a pulse width between approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms, since applicant has not disclosed that these particular bi-phasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform pulse width such as approximately 6.5 ms to approximately 24.5 ms taught by KenKnight and Herscovici for pacing the heart.

13. Claims 85-86, and 115-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Herscovici (4,534,956) and further in view of Florio et al. (6,519,493). KenKnight and Herscovici is as explained before.

Although KenKnight and Herscovici fails to shows the bi-phasic pacing pulses are applied at a rate of approximately 100 to approximately 300 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the pacing pulses of KenKnight and Herscovici at a rate of 155 bpm or more after detection of a tachycardia or 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

14. Claims 62-63 75, 80-81, 83, 92-93, 105, 110-111, and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Stein (4,406,286). Although KenKnight fails to show utilizing a bi-phasic pacing pulse, attention is directed to Stein who shows utilizing a bi-phasic pacing pulse having a positive and negative pulse and a peak voltage of approximately 5 V to approximately 500V and approximately 5 V to approximately 25V and a duration of from approximately 2 ms to approximately 40 ms and the negative and positive portions having a tilt from 10% to 90% (Fig. 3; Col 4, lines 2-7, lines 41-43; Col. 6, lines 51-66). Stein teaches that utilizing a bi-phasic waveform reduces stimulation levels at the input of sense amplifiers (Col. 2, line 64- Col. 3, line 2). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize a bi-phasic pacing pulse having a positive and negative pulse and a peak voltage of approximately 5 V to approximately 500 V, or approximately 5 V to approximately 25 V and a duration of

from approximately 2 ms to approximately 40 ms, and a tilt of 10% to 90% as Stein teaches in order to reduce stimulation levels at the input of sense amplifiers.

15. Claims 64-74, 76-79, 82 84, 94-104, 106-109, 112, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Stein (4,406,286). KenKnight and Stein are as explained before.

Regarding claims 64-74 and 94-104, KenKnight and Stein disclose the claimed invention except for the bi-phasic waveform has a peak voltage of approximately 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, approximately 75 Volts to approximately 100 Volts, approximately 100 Volts to approximately 150 Volts, approximately 150 Volts to approximately 200 Volts, approximately 200 Volts to approximately 250 Volts, approximately 250 Volts to approximately 300 Volts, approximately 300 Volts to approximately 350 Volts, approximately 350 Volts to approximately 400 Volts, approximately 400 Volts to approximately 450 Volts, and approximately 450 Volts to approximately 500 Volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the bi-phasic waveform peak voltage as taught by KenKnight and Stein with bi-phasic waveform peak voltages of 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, approximately 75 Volts to approximately 100 Volts, approximately 100 Volts to approximately 150 Volts, approximately 150 Volts to approximately 200 Volts, approximately 200 Volts to approximately 250 Volts, approximately 250 Volts to approximately 300 Volts, approximately 300 Volts to approximately 350 Volts, approximately 350 Volts to approximately 400 Volts, approximately 400 Volts to

approximately 450 Volts, and approximately 450 Volts to approximately 500 Volts since applicant has not disclosed that these particular bi-phasic waveform peak voltages provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform peak voltage such as 5.6 V taught by KenKnight and Stein for pacing the heart.

With respect to claims 77-79, and 107-109, KenKnight and Stein disclose the claimed invention except for the bi-phasic waveform having a pulse width between approximately 2 ms and approximately 10 ms, approximately 10 ms and approximately 20 ms, approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify bi-phasic waveform pulse width as taught by KenKnight and Stein with bi-phasic waveforms having a pulse width between approximately 2 ms and approximately 10 ms, approximately 10 ms and approximately 20 ms, approximately 20 ms and approximately 30 ms, approximately 30 ms and approximately 40 ms, since applicant has not disclosed that these particular bi-phasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform pulse width such as approximately 6.5 ms to approximately 24.5 ms taught by KenKnight and Stein for pacing the heart.

Regarding claims 82, 84,112, and 114, KenKnight and Stein discloses the claimed invention except for the positive and negative voltage portion of the bi-phasic waveform having a tilt of 50%. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the tilt of the positive and

negative voltage portion of the bi-phasic waveform as taught by KenKnight and Stein with a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any tilt such as the 10%-90% tilt taught by KenKnight and Stein for applying pacing pulses.

16. Claims 85-86, 115, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Stein (4,406,286) and further in view of Florio et al. (6,519,493). KenKnight and Stein is as explained before. Although KenKnight and Stein fail to shows the bi-phasic pacing pulses are applied at a rate of approximately 100 to approximately 300 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the pacing pulses of KenKnight and Stein at a rate of 155 bpm or more after detection of a tachycardia or 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

17. Claims 90, and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Causey III et al. (5,318,591). KenKnight is as explained before. Although KenKnight fails to show the pacing energy comprises ramp pacing energy, attention is directed to Causey III et al. which teaches ramp pacing energy is well known (Col. 1, lines 32-41). Therefore, it would have been obvious to one with

ordinary skill in the art at the time the invention was made to utilize ramp pacing energy since it is well known in the art.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-24, 31-54, 61-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24, 27-50, 53-76 of copending Application No. 09/940378. Although the conflicting claims are not identical, they are not patentably distinct from due to the fact that the only claimed difference is intended use.

20. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kerver et al (5,964,787) shows a pacer that generates bi-phasic stimulation pulses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld

KENNEDY SCHAETZLE
PRIMARY EXAMINER
10-1-03